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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Martin Debreczeny	§	Confirmation No. :	8831
Serial No.: 10/820,637	§	Group Art Unit:	3768
Filed: April 07, 2004	§	Examiner:	Winakur, Eric Frank
For: PHOTOPLETHYSMOGRAPHY WITH A SPATIALLY HOMOGENOUS MULTI-COLOR SOURCE	§	Atty. Docket:	TYHC:0041/FLE/RAR/COH P0396R

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January 30, 2009 — Jessie Hebert
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APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance of the Notice of Appeal filed on December 2, 2008. This Appeal Brief is in response to the Final Office Action mailed on October 16, 2008.

Appellant is paying the requisite fee of $540.00 for this Appeal Brief, and any additional fees which may be necessary to advance prosecution of the present application, electronically at the time of filing this Appeal Brief. However, if the amount provided is insufficient, or if the amount is unable to be charged to the credit card provided for the electronic payment for any other reason, the Commissioner is authorized to charge such fees to Deposit Account No. 06-1315, Order No. TYHC:0041. Further, in accordance with 37 C.F.R. § 1.136, Appellant hereby provides a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefore

and authorize the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 06-1315, Order No. TYHC:0041.

1. REAL PARTY IN INTEREST

The real party in interest is Nellcor Puritan Bennett LLC. The above-referenced application was assigned to Nellcor Puritan Bennett Incorporated by virtue of the Assignment recorded at reel 015678, frame 0471, and recorded on August 16, 2004. Nellcor Puritan Bennett Incorporated became Nellcor Puritan Bennett LLC on December 29, 2006. Accordingly Nellcor Puritan Bennett LLC will be directly affected by the Board's decision in this Appeal.

2. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any other appeals or interferences related to this appeal. The undersigned is Appellant's legal representative in this appeal.

3. STATUS OF CLAIMS

Claims 1-20 are currently pending, are currently under final rejection, and are the subject of this appeal.

4. STATUS OF AMENDMENTS

The instant claims have not been amended subsequent to the Final Office Action mailed October 16, 2008. Consequently, there are no outstanding amendments to be considered by the Board.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates generally to the field of photoplethysmography and, more specifically, to a sensor which directs electromagnetic energy from multiple sources to a tissue location for the purpose of measuring a physiological parameter. *See, e.g.*, Specification, page 1, lines 5-8. The present application contains six independent claims,

namely claims 1, 5, 13, 15, 19, and 20, all of which have been improperly rejected and, thus, are subject to this appeal. The subject matter of the independent claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a physiological sensor. *See, e.g.,* Specification, page 3, lines 23-24; *see also, e.g.,* Specification, page 7, lines 18-19. The physiological sensor may include a first inlet (e.g. 202) configured to receive electromagnetic energy transmitted from a first source (e.g. light source 1) and a second inlet (e.g. 204) configured to receive electromagnetic energy transmitted from a second source (e.g. light source 2). *See, e.g., id.* at page 6, lines 31-33. The physiological sensor may further include means for spatially homogenizing the electromagnetic energy transmitted from the first source with the electromagnetic energy transmitted from the second source in a non-random configuration to form a spatially-homogenized multi-source electromagnetic energy configured to enable measurement of a physiological parameter of a subject. *See, e.g.,* Application, FIG. 2; *see also, e.g.,* Response and Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022]. Finally, the physiological sensor may include an outlet (e.g. 206) configured to deliver the spatially-homogenized multi-source electromagnetic energy to a tissue location of the subject (e.g. 112) for measurement of the physiological parameter. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1.

With regard to the aspect of the invention set forth in independent claim 5, discussions of the recited features of claim 5 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a physiological sensor. *See, e.g.,* Specification, page 3, lines 23-24; *see also, e.g.,* Specification, page 7, lines 18-19. The

physiological sensor may include a first source of electromagnetic energy (e.g. light source 1) and a second source of electromagnetic energy (e.g. light source 2). *See, e.g., id.* at page 6, lines 31-33. The physiological sensor may further include an apparatus (e.g. 200) configured to spatially homogenize electromagnetic energy transmitted from the first and second sources. *See, e.g., id.* at page 6, lines 29-31. The apparatus may include a first inlet (e.g. 202) configured to receive electromagnetic energy transmitted from the first source and a second inlet (e.g. 204) configured to receive electromagnetic energy transmitted from the second source. *See, e.g., id.* at page 6, lines 31-33. In addition, the apparatus may include means for spatially homogenizing the electromagnetic energy transmitted from the first source with the electromagnetic energy transmitted from the second source in a non-random configuration to form a spatially-homogenized multi-source electromagnetic energy. *See, e.g.,* Application, FIG. 2; *see also, e.g.,* Response and Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022]. Finally, the apparatus may include an outlet (e.g. 206) configured to deliver the spatially-homogenized multi-source electromagnetic energy to a blood-perfused tissue location (e.g. 112) and light detection optics (e.g. 114) configured to receive the spatially-homogenized multi-source electromagnetic energy from the blood-perfused tissue location for measuring the physiological parameter. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1.

With regard to the aspect of the invention set forth in independent claim 13, discussions of the recited features of claim 13 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a physiological sensor. *See, e.g.,* Specification, page 3, lines 23-24; *see also, e.g.,* Specification, page 7, lines 18-19. The physiological sensor may include a first plurality of optical fibers (e.g. 210) configured to receive and to transmit electromagnetic energy from a first source (e.g. light source 1), the first plurality of optical fibers having proximal ends and distal ends, and a second plurality of optical fibers (e.g. 220) configured to receive and to transmit electromagnetic energy from a second source (e.g. light source 2), the second plurality of optical fibers also having

also having proximal ends and distal ends. The proximal ends of the second plurality of optical fibers (e.g. 220) may be segregated from the proximal end of the first plurality of optical fibers (e.g. 210). In addition, the physiological sensor may include an outlet (e.g. 206) configured to emit a spatially homogenized electromagnetic energy into a tissue location of a subject (e.g. 112) to enable measurement of a physiological parameter, the outlet comprising the distal ends of the first plurality of optical fibers arranged in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers. *See, e.g.,* Application, FIG. 2; *see also, e.g.,* Response and Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022].

With regard to the aspect of the invention set forth in independent claim 15 , discussions of the recited features of claim 15 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a system comprising having a first source of electromagnetic energy (e.g. light source 1), a second source of electromagnetic energy (e.g. light source 2), a monitor (e.g. 120) configured to calculate a physiological parameter, and a sensor (e.g. 100) adapted to be operatively coupled to the monitor. *See, e.g.,* Specification, page 5, line 9 – page 6, line 20. The sensor may include a first plurality of optical fibers (e.g. 210) configured to receive and to transmit electromagnetic energy from the first source, the first plurality of optical fibers having proximal ends and distal ends, and a second plurality of optical fibers (e.g. 220) configured to receive and to transmit electromagnetic energy from the second source, the second plurality of optical fibers having proximal ends and distal ends. *See, e.g.,* Application, FIG. 2. The proximal ends of the first plurality of optical fibers may be segregated from the proximal ends of the second plurality of optical fibers, and the distal ends of the first plurality of optical fibers may arranged in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers such that the transmitted electromagnetic energy from the first source is spatially homogenized with the transmitted electromagnetic energy from the second source. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1; Application, FIG. 2; Response and Amendment to the

Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022].

With regard to the aspect of the invention set forth in independent claim 19 , discussions of the recited features of claim 19 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method of manufacturing a physiological sensor (e.g. 100). The method may include providing a first plurality of optical fibers (e.g. 210) configured to receive and to transmit electromagnetic energy from a first source (e.g. light source 1), the first plurality of optical fibers having proximal ends and distal ends, and providing a second plurality of optical fibers (e.g. 220) configured to receive and to transmit electromagnetic energy from a second source (e.g. light source 2), the second plurality of optical fibers having proximal ends and distal ends. *See, e.g.,* Application, FIG. 2. The method may further include arranging the distal ends of the first plurality of optical fibers in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers such that transmitted electromagnetic energy is spatially homogenized at an outlet (e.g. 206) of the sensor. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1; Application, FIG. 2; Response and Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022]. Finally, the method may include providing light detection optics (e.g. 114) configured to detect attenuation of the spatially homogenized electromagnetic energy emitted from the outlet. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1.

With regard to the aspect of the invention set forth in independent claim 20 , discussions of the recited features of claim 20 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method of measuring a physiological parameter. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1. The method may include transmitting electromagnetic energy from a first source (e.g. light source 1) through a first plurality of optical fibers (e.g. 210)

configured to receive and to transmit the electromagnetic energy, the first plurality of optical fibers having proximal ends and distal ends, and transmitting electromagnetic energy from a second source (e.g. light source 2) through a second plurality of optical fibers (e.g. 220) configured to receive and to transmit the electromagnetic energy, the second plurality of optical fibers having proximal ends and distal ends. *See, e.g.,* Application, FIG. 2. The method may further include outputting spatially homogenized electromagnetic energy of the first and the second source from an outlet region (e.g. 206) comprising the distal ends of the first and second plurality of optical fibers, wherein the distal ends are arranged in a non-random configuration. Application, FIG. 2; *see also, e.g.,* Response and Amendment to the Office Action mailed on January 23, 2007, page 3, amended ¶ [0022]. Finally, the method may include detecting attenuation of the output spatially homogenized electromagnetic energy at a tissue location (e.g. 112) and determining a physiological parameter based on the detected attenuation. *See, e.g.,* Specification, page 1, lines 9-29; *see also, e.g.,* Specification, page 8, line 20 – page 9, line 1.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection

The Examiner rejected claims 1-4 and 13 under 35 U.S.C. § 102(b) as being anticipated by Reynolds (U.S. Patent App. No. 3,825,335). Final Office Action, page 2.

Second Ground of Rejection

The Examiner rejected claims 5-9, 11-16, and 18-20 under 35 U.S.C. § 103(a) as obvious over Vari et al. (U.S. Patent No. 5,701,902) in view of Reynolds. *Id.*

Third Ground of Rejection

The Examiner rejected claims 10 and 17 under 35 U.S.C. § 103(a) as obvious over Vari and Reynolds in view of Jeffcoat et al. (U.S. Patent No. 5,036,853). *Id.*

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C. §§ 102(b) and 103(a). Accordingly, Appellant respectfully requests full and favorable consideration by the Board, as Appellant strongly believes that claims 1-20 are currently in condition for allowance.

First Ground of Rejection

As noted above, the Examiner rejected claims 1-4 and 13 under 35 U.S.C. § 102(b) as anticipated by the Reynolds reference. Appellant respectfully submits that the present claims recite features not disclosed in the cited reference. Accordingly, Appellant requests that the Board overturn the Examiner's rejection of the present claims.

Legal Precedent and Guidelines

Anticipation under 35 U.S.C. § 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). For a prior art reference to anticipate under 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). To maintain a proper rejection under 35 U.S.C. § 102, a single reference must teach each and every limitation of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Accordingly, Appellant needs only point to a single element not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter. The prior art reference also must show the identical invention "in as complete detail as contained in the ... claim" to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

In addition, in interpreting claims, a determination of whether a claim preamble limits the claim is made on a case-by-case basis. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Regarding the preamble of a claim, terminology that limits the structure of the claimed invention must be treated as a claim limitation. M.P.E.P § 2111.02; *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251 (Fed. Cir. 1989); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796 (Fed. Cir. 1990); *In re Stencel*, 828 F.2d 751 (Fed. Cir. 1987). Furthermore, the determination of whether the preamble recites a structural limitation or a statement of purpose/use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works,* 868 F.2d at 1257; M.P.E.P § 2111.02. Terms recited in the preamble must also be given their "plain meaning" unless such meaning is inconsistent with the specification. M.P.E.P. § 2111.01.

Claim Features of Independent Claim 1 Omitted from Cited Reference

Turning to the claims, independent claims 1 recites, *inter alia*, a "physiological sensor." (Emphasis added). Regarding amendments to claim 1 presented in the Request for Continuing Examination, Amendment, and Response to Office Action mailed on October 18, 2007, the Examiner stated that "the amended preamble does not appear to impose any structural limitations on the claimed elements, and those claimed elements remain structurally indistinguishable from those of Reynolds." Office Action mailed on April 2, 2008, page 3. However, despite the Examiner's argument that the preamble does not provide a structural limitation, recitation of a physiological sensor constitutes a structure (i.e., not a function) in that a physiological sensor is a physical structure which can be distinguished from other structures that are not physiological sensors (e.g., windows, trees, apples, desks, and so forth). That is, a sensor is a specific type of structure, and a reference that does not disclose a sensor cannot anticipate the present claims. The Reynolds reference does not disclose a physiological sensor and therefore cannot anticipate the presently recited sensor.

In addition, the body of independent claim 1 recites, *inter alia*:

> means for spatially homogenizing the electromagnetic energy transmitted from the first source with the electromagnetic energy transmitted from the second source in a non-random configuration to form a spatially-homogenized multi-source electromagnetic energy configured to enable measurement of a physiological parameter of a subject; and
>
> an outlet configured to deliver the spatially-homogenized multi-source electromagnetic energy to a tissue location of the subject for the measurement of the physiological parameter.

(Emphasis added). That is, the sensor outlet must be adapted to direct the spatially homogenized electromagnetic energy to a subject's tissue in such a way to enable measurement of a physiological parameter. The Examiner failed to identify how the variable lighting system for photography disclosed in the Reynolds reference is configured to enable measurement of a physiological parameter. On the contrary, the cited reference merely includes colored lights for illuminating a scene for color photography. *See* Reynolds, col. 1, lines 7-10. Accordingly, the Reynolds reference clearly does not disclose or suggest the recited physiological sensor including means for spatially homogenizing electromagnetic energy from first and second sources to enable measurement of a physiological parameter.

For at least these reasons, the Reynolds reference does not anticipate independent claim 1 or its dependent claims. Appellant therefore respectfully requests that the Board overturn the rejection of claims 1-4 under 35 U.S.C. § 102.

Claim Features of Independent Claim 13 Omitted from Cited Reference

Similarly to independent claim 1, independent claim 13 recites a "physiological sensor." (Emphasis added). Again, the Examiner seems to have disregarded the preamble in evaluating the present claim. That is, the Reynolds reference clearly does not disclose a physiological sensor. Furthermore, claim 13 recites, *inter alia*, "an outlet configured to emit a spatially homogenized electromagnetic energy into a tissue location of a subject to

of a subject to enable measurement of a physiological parameter." (Emphasis added). Once more, the Examiner failed to identify in Reynolds an outlet adapted to direct spatially homogenized electromagnetic energy to a subject's tissue to enable measurement of a physiological parameter. Rather, the cited reference discloses colored lights for illuminating a scene for color photography. *See* Reynolds, col. 1, lines 7-10. The Reynolds reference therefore clearly does not disclose or suggest the recited physiological sensor having an outlet for spatially homogenized electromagnetic energy from first and second sources which enables measurement of a physiological parameter.

For at least these reasons, the Reynolds reference does not anticipate independent claim 13 or its dependent claims. Appellant therefore respectfully requests that the Board overturn of the rejection of claim 13 under 35 U.S.C. § 102.

Second and Third Grounds of Rejection

As previously noted, the Examiner rejected claims 5-9, 11-16, and 18-20 under 35 U.S.C. § 103(a) as obvious over the Vari reference in view of the Reynolds reference. The Examiner also rejected claims 10 and 17 under 35 U.S.C. § 103(a) as obvious over the Vari and Reynolds references in further view of the Jeffcoat reference. Appellant respectfully asserts that the Examiner has improperly combined non-analogous references in the present rejection. In addition, Appellant respectfully submits that even if the cited references can be considered analogous art, which Appellant does not concede, combination of the Vari and Reynolds references is improper, and the Jeffcoat reference does not obviate the deficiencies of the Vari and Reynolds references. Accordingly, Appellant requests that the Board overturn the Examiner's rejection of the present claims under 35 U.S.C. § 103.

Legal Precedent and Guidelines

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested

be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). However, a claimed invention composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The *KSR* court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* Specifically, there must be some articulated reasoning with a rational underpinning to support a conclusion of obviousness; a conclusory statement will not suffice. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). Indeed, the factual inquiry determining whether to combine references must be thorough and searching, and it must be based on objective evidence of record. *In re Lee,* 61 U.S.P.Q.2d 1430, 1436 (Fed. Cir. 2002).

Furthermore, there must be some reason to combine references other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The Federal Circuit has warned that the Examiner must not, "fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *In re Dembiczak*, F.3d 994, 999 (Fed. Cir. 1999) (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)).

In addition, non-analogous art cannot properly be pertinent prior art under 35 U.S.C. § 103. *In re Pagliaro*, 210 U.S.P.Q. 888, 892 (C.C.P.A. 1981). For the teachings of a reference to be prior art under 35 U.S.C. § 103, there must be some basis for concluding that the reference would have been considered by one skilled in the particular

art working on the particular problem with which the invention pertains. *In re Horne*, 203 U.S.P.Q. 969, 971 (C.C.P.A. 1979). The determination of whether a reference is from a non-analogous art is set forth in a two-step test given in *Union Carbide Corp. v. American Can Co.*, 724 F.2d 1567 (Fed. Cir. 1984). In *Union Carbide*, the court found that the first determination was whether "the reference is within the field of the inventor's endeavor." If it is not, one must proceed to the second step "to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved." In regard to the second step, *Bott v. Four Star Corp.*, 218 U.S.P.Q. 358 (E.D. Mich. 1983), determined that "analogous art is that field of art which a person of ordinary skill in the art would have been apt to refer in attempting to solve the problem solved by a proposed invention." In addition, a relevant area of art "should be where one of ordinary skill in the art would be aware that similar problems exist." *Id.*

Reynolds is Non-Analogous Art

Based on the foregoing two-part non-analogous art test, the Reynolds reference does not qualify as analogous art. In regard to the first step of the *Union Carbide* test, the photographic lighting system of Reynolds is clearly not in the field of Appellant's endeavor. That is, a lighting system for color photography is not related to a sensor for measuring a physiological parameter of a patient.

In regard to the second step of the *Union Carbide* test, the photographic lighting system of the Reynolds reference is not reasonably pertinent to the problem with which Appellant was involved. The present application is related to homogenizing electromagnetic energy output from a medical sensor to a tissue location for the purpose of measuring a physiological parameter. *See* Specification, page 1, lines 5-8. That is, the scope of the present application is directed to homogenizing electromagnetic energy which may be used in the measurement of a physiological parameter; such energy is often times not even in the visible spectrum. *See id.* at page 7, line 27 – page 8, line 5. In addition, the homogeneity problem addressed by the present application is related to homogeneity at a tissue location. *See id.* at page 2, lines 5-13. The homogeneity of light at the outlet of the

at the outlet of the sensor is relevant only in the respect that the outlet of the sensor is in very close proximity to the tissue location, and therefore homogeneity at the tissue location may be reasonably anticipated by homogeneity at the sensor outlet.

In contrast, the Reynolds reference is related to illuminating a scene with a desired color to enhance color photography. *See* Reynolds, Abstract. In arguing that Reynolds is analogous art, the Examiner framed the problem to be solved as "homogenizing electromagnetic energy that has been transmitted through optical fibers" and argued that any art involving lights would therefore be relevant. Final Office Action, page 4. However, one must also consider whether one skilled in the art "would have been apt to refer [to the art] in attempting to solve the problem solved by a proposed invention." *Bott*, 218 U.S.P.Q. 358. There is no objective reason that one skilled in the art of physiological sensors would consider a color photography lighting system in attempting to solve problems associated with the measurement of physiological parameters. That is, the variable color lighting system of Reynolds has no bearing on the problem of inputting homogeneous light into a tissue location solved by the present disclosure. Thus, there is no evidence whatsoever that similar problems exist in these disparate fields of art.

Accordingly, the Reynolds reference is believed to be non-analogous art. Appellant respectfully requests that the Board remove the Reynolds reference from consideration. Furthermore, because the Examiner relied on the Reynolds reference in all of the rejections under 35 U.S.C. § 103, Appellant respectfully requests that the Board overturn the rejection of claims 5-20.

Cited References are not Properly Combinable

Furthermore, even if, *arguendo*, the Reynolds reference is not non-analogous art, which Appellant does not concede, the Examiner has not made a *prima facie* case of obviousness regarding the combination of the Reynolds, Vari, and/or Jeffcoat references.

In initially rejecting the present claims in view of Vari and Reynolds, the Examiner stated that "Vari et al. teach that the optical fibers are randomly mixed." Office Action mailed October 18, 2007, page 2. In addition, the Examiner stated that Reynolds "teaches that a non-random (alternating , ordered array) arrangement of optical fibers from multiple sources has an intermixed, composite output." *Id.* at pages 2-3. The Examiner therefore concluded that one skilled in the art would find it obvious to substitute the ordered fiber arrangement of Reynolds for the random arrangement of Vari. However, the Examiner failed to identify anything in the prior art references which teaches or suggests that the different fiber configurations are equivalent. Specifically, the Manual of Patent Examining Procedure states, "In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." M.P.E.P § 2144.06 (citing *In re Ruff*, 256 F.2d 590 (CCPA 1958)) (emphasis added). For at least this reason, the Examiner has not set forth a *prima facie* case of obviousness regarding claims 5-20, and therefore Appellant respectfully requests the Board overturn the rejection of the present claims.

In addition, the Examiner has not provided any objective evidence of a reason to combine the Vari and Reynolds references. Specifically, the Vari reference teaches random dispersion of optical fiber bundles 48-54. *See* Vari et al., col. 5, lines 24-27. In contrast, the Reynolds reference specifically discloses ordered distribution of optical fibers carrying red, green, and blue light. *See* Reynolds, col. 6, lines 43-48. The Examiner suggested that these references teach alternative manners in which to achieve the same result and therefore can be interchanged/combined. However, as the Examiner argued that each reference provides a different method to solve an electromagnetic energy homogeneity problem, there is clearly no reason to combine the references. That is, because there is not a problem in one reference, it is not reasonable to seek an alternate solution from another reference, i.e., there is no objective reason to modify the reference in question. The only reason the Examiner could have for suggesting that these references are

argued that each reference provides a different method to solve an electromagnetic energy homogeneity problem, there is clearly no reason to combine the references. That is, because there is not a problem in one reference, it is not reasonable to seek an alternate solution from another reference, i.e., there is no objective reason to modify the reference in question. The only reason the Examiner could have for suggesting that these references are combinable is to improperly disparage the present application based on hindsight analysis. For at least this reason, the proposed combination is improper and must be withdrawn.

In addition, the Jeffcoat reference, combined with either the Vari reference or the Reynolds reference, does not obviate the deficiencies of either reference with regard to disclosing all elements of the independent claims. On the contrary, the Jeffcoat reference does not address the spatial arrangement of the bundled optical fibers in the probe 100. *See* Jeffcoat et al., col. 4, lines 57-61. In view of these deficiencies, among others, Appellant respectfully requests withdrawal of the rejection of claims 5-20 under 35 U.S.C. § 103.

Conclusion

In view of the remarks set forth above, Appellant respectfully requests that the Board overturn Examiner's rejections and provide an indication of allowance of all pending claims. If the Board believes that a telephonic interview will help speed this application toward issuance, the Board is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: January 30, 2009

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8. APPENDIX OF CLAIMS ON APPEAL

1. A physiological sensor, comprising:

a first inlet configured to receive electromagnetic energy transmitted from a first source;

a second inlet configured to receive electromagnetic energy transmitted from a second source;

means for spatially homogenizing the electromagnetic energy transmitted from the first source with the electromagnetic energy transmitted from the second source in a non-random configuration to form a spatially-homogenized multi-source electromagnetic energy configured to enable measurement of a physiological parameter of a subject; and

an outlet configured to deliver the spatially-homogenized multi-source electromagnetic energy to a tissue location of the subject for the measurement of the physiological parameter.

2. The physiological sensor of claim 1 wherein the means for spatially homogenizing comprises:

a first bundle of optical fibers having a first proximal end originating at the first inlet and a first distal end terminating at the outlet; and

a second bundle of optical fibers having a second proximal end originating at the second inlet and a second distal end terminating at the outlet;

wherein each first distal end of each fiber of the first bundle of fibers is spatially mixed in an alternating configuration with each second distal end of each fiber of the second bundle of fibers, so as to form a spatially-homogenized multi-source electromagnetic energy at the outlet.

3. The physiological sensor of claim 2 comprising a cladding surrounding the first bundle and the second bundle of optical fibers, the cladding having a first cladding

proximal end at the first inlet, a second cladding proximal end at the second inlet and a cladding outlet at the outlet.

4. The physiological sensor of claim 1 wherein:

the electromagnetic energy from the first source is in a first spectral region;

the electromagnetic energy from the second source is in a second spectral region, wherein the second spectral region is different from the first spectral region; and

the spatially-homogenized multi-source electromagnetic energy is a spatially-homogenized multi-spectral electromagnetic energy.

5. A physiological sensor, comprising:

a first source of electromagnetic energy;

a second source of electromagnetic energy;

an apparatus configured to spatially homogenize electromagnetic energy transmitted from the first and second sources, the apparatus comprising:

a first inlet configured to receive electromagnetic energy transmitted from the first source;

a second inlet configured to receive electromagnetic energy transmitted from the second source;

means for spatially homogenizing the electromagnetic energy transmitted from the first source with the electromagnetic energy transmitted from the second source in a non-random configuration to form a spatially-homogenized multi-source electromagnetic energy; and

an outlet configured to deliver the spatially-homogenized multi-source electromagnetic energy to a blood-perfused tissue location; and

light detection optics configured to receive the spatially-homogenized multi-source electromagnetic energy from the blood-perfused tissue location for measuring the physiological parameter.

6. The physiological sensor of claim 5 wherein the means for spatially homogenizing comprises:

a first bundle of optical fibers having a first proximal end originating at the first inlet and a first distal end terminating at the outlet;

a second bundle of optical fibers having a second proximal end originating at the second inlet and a second distal end terminating at the outlet;

wherein at the outlet each first distal end of each fiber of the fibers of the first bundle is spatially mixed in an alternating configuration with each second distal end of each fiber of the fibers of the second bundle, so as to form a spatially-homogenized multi-source electromagnetic energy received from the first and the second inlets.

7. The physiological sensor of claim 6 comprising a cladding surrounding the first bundle and the second bundle of optical fibers, the cladding having a first cladding proximal end at the first inlet, a second cladding proximal end at the second inlet and a cladding outlet at the outlet.

8. The physiological sensor of claim 5 wherein:

the first source transmits electromagnetic energy in a first spectral region;

the second source transmits electromagnetic energy in a second spectral region; and

the spatially-homogenized multi-source electromagnetic energy is a spatially-homogenized multi-spectral electromagnetic energy.

9. The physiological sensor of claim 8 wherein the first source and the second source are configured to transmit electromagnetic energy in the range approximately between 500 and 1850 nm.

10. The physiological sensor of claim 8, wherein the first source is configured to transmit electromagnetic energy at approximately 660 nm.

11. The physiological sensor of claim 8 wherein the second source is configured to transmit electromagnetic energy in the range approximately between 890 and 940 nm.

12. The physiological sensor of claim 5 wherein the sensor is an oximeter sensor.

13. A physiological sensor, comprising:

a first plurality of optical fibers configured to receive and to transmit electromagnetic energy from a first source, the first plurality of optical fibers having proximal ends and distal ends;

a second plurality of optical fibers configured to receive and to transmit electromagnetic energy from a second source, the second plurality of optical fibers having proximal ends and distal ends, wherein the proximal ends of the second plurality of optical fibers are segregated from the proximal end of the first plurality of optical fibers; and

an outlet configured to emit a spatially homogenized electromagnetic energy into a tissue location of a subject to enable measurement of a physiological parameter, the outlet comprising the distal ends of the first plurality of optical fibers arranged in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers.

14. The physiological sensor of claim 13, comprising light detection optics to receive the spatially homogenized electromagnetic energy emitted from the outlet.

15. A system comprising:

a first source of electromagnetic energy;

a second source of electromagnetic energy;

a monitor configured to calculate a physiological parameter; and

a sensor adapted to be operatively coupled to the monitor, the sensor comprising:

a first plurality of optical fibers configured to receive and to transmit electromagnetic energy from the first source, the first plurality of optical fibers having proximal ends and distal ends; and

a second plurality of optical fibers configured to receive and to transmit electromagnetic energy from the second source, the second plurality of optical fibers having proximal ends and distal ends;

wherein the proximal ends of the first plurality of optical fibers are segregated from the proximal ends of the second plurality of optical fibers, and wherein the distal ends of the first plurality of optical fibers are arranged in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers such that the transmitted electromagnetic energy from the first source is spatially homogenized with the transmitted electromagnetic energy from the second source.

16. The system of claim 15, wherein the first source and the second source are configured to transmit electromagnetic energy in the range approximately between 500 and 1850 nm.

17. The system of claim 15, wherein the first source is configured to transmit electromagnetic energy at approximately 660 nm.

18. The system of claim 15, wherein the second source is configured to transmit electromagnetic energy in the range approximately between 890 and 940 nm.

19. A method of manufacturing a physiological sensor, the method comprising:

providing a first plurality of optical fibers configured to receive and to transmit electromagnetic energy from a first source, the first plurality of optical fibers having proximal ends and distal ends;

providing a second plurality of optical fibers configured to receive and to transmit electromagnetic energy from a second source, the second plurality of optical fibers having proximal ends and distal ends;

arranging the distal ends of the first plurality of optical fibers in a spatially mixed non-random configuration with the distal ends of the second plurality of optical fibers such that transmitted electromagnetic energy is spatially homogenized at an outlet of the sensor; and

providing light detection optics configured to detect attenuation of the spatially homogenized electromagnetic energy emitted from the outlet.

20. A method of measuring a physiological parameter, comprising:

transmitting electromagnetic energy from a first source through a first plurality of optical fibers configured to receive and to transmit the electromagnetic energy, the first plurality of optical fibers having proximal ends and distal ends;

transmitting electromagnetic energy from a second source through a second plurality of optical fibers configured to receive and to transmit the electromagnetic energy, the second plurality of optical fibers having proximal ends and distal ends;

outputting spatially homogenized electromagnetic energy of the first and the second source from an outlet region comprising the distal ends of the first and second plurality of optical fibers, wherein the distal ends are arranged in a non-random configuration;

detecting attenuation of the output spatially homogenized electromagnetic energy at a tissue location; and

determining a physiological parameter based on the detected attenuation.

9. **APPENDIX OF EVIDENCE**

None.

10. APPENDIX OF RELATED PROCEEDINGS

None.